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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,856	03/26/2004	Osama Kandil	KAN-002-B	7581

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EXAMINER	
LEITH, PATRICIA A	
ART UNIT	PAPER NUMBER
1655	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/809,856	KANDIL, OSAMA	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *6-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-24 are pending in the application, claims 23 and 24 being newly added in the most recent amendment filed on 11/01/06.

Claims 6-19 were withdrawn from examination on the merits as they are drawn to an invention nonelected with traverse the response filed on 05/05/06.

Claims 1-5 and 20-24 were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 20-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites 'primarily composed of unsaturated C18 fatty acids selected from the group consisting of linoleic acid, oleic acid and linolenic acid'. This new limitation to claim 1 is considered New Matter in that it cannot be found where the Description as originally filed, explicitly or implicitly taught this information. Although the disclosure teaches that the lipid fraction is primarily composed of long chain fatty acids, sterols and volatile oils, it cannot be found wherein the lipid fraction is primarily composed of linoleic, oleic or linolenic acid. It is deemed that the newly added limitation to claim 1 changes the scope of the invention as originally described and therefore constitutes New Matter. Applicant is asked to either point out where in the original disclosure this information can be found or to amend/delete the pertinent claim language in order to overcome this rejection.

Because claims 2-5 and 20-24 depend directly or indirectly upon claim 1, claims 2-5 and 20-24 necessarily possess all of the limitations of claim 1 and are thus properly rejected under this statute.

Rejections presented in the previous Office Action have been removed due to Applicant's amendments to the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Ramadan and Mörsel (Nahrung/Food) (2002).

Ramadan and Mörsel (Nahrung/Food) (2002) studied the *in-vivo* toxicity of *Nigella sativa* fixed oil prepared by hexane extraction on *lops ofa* mice, wherein one group received the *Nigella sativa* fixed oil mixed with gum acacia (considered a pharmaceutical carrier) (see for example, pp. 240-241, Experimental, p. 241 and Table 2 p. 242).

Nigella sativa fixed oil prepared by hexane extraction contains approximately 60% linoleic acid and approximately 20% of oleic acid as evidenced by Table 2 of Ramadan.

It is deemed that the mixture of 5% acacia and *Nigella sativa* oil could be used as an ointment or a balm and therefore Ramadan et al. anticipate claim 2.

Claim Rejections - 35 USC § 103

Claims 1-5 and 20-24 are ejected under 35 U.S.C. 103(a) as being unpatentable over Kandil (US 2002/0132019 A1) in view of Ramadan and Mörsel (Nahrung/Food) (2002).

It is clear that Kandil US 2002/0132019 A1 (Applicant's application published September 19, 2002) disclosed the oil fraction of *N. sativa* (see figure 1).

The reference does not specifically teach wherein the composition was added to a pharmaceutical carrier.

The oil of *Nigella sativa* seeds has been known to display medicinal characteristics , and has been widely consumed (see Ramadan et al., Introduction). Further, Ramadan et al. clearly taught the necessity for testing the toxicity of different oil fractions (see pp. 240-241, Experimental, p. 241 and Table 2 p. 242).

One of ordinary skill in the art would have been motivated to formulate the composition disclosed by Kandill in Figure 1 with a pharmaceutical carrier in order to

ease administration of the composition or alternatively, to dilute the oil for further toxicity testing.

Applicant's arguments were fully considered, and found persuasive in-part.

Applicant's arguments pertaining to wherein Kandill did not teach a use of the oil fraction of Figure 1 is accepted; hence the new rejection set forth *supra*.

Applicant's principal argument is that the Kandill publication fails to provide an enabling reference and cites *In re Hoeksema* ("...the stated test is whether a reference contains an "enabling disclosure" as well as *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Reasearch* "The disclosure....mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation" and *In re Donohue*: "A reference contains an "enabling disclosure' if the public was in possession of the claimed invention before the date of invention...." (p. 9, Remarks).

Applicant argues that the Kandil describes the intermediate lipid fraction as a 'petroleum ether or hexane extract' and "Given the teachings of Haresh et al., one would expect such an extract to be primarily comprised of palmitic acid, a C16 saturated fatty acid".

First, it is noted that upon further research of *N.sativa* seed oil content, it is deemed that the Haresh et al. (used in a previous rejection) data with regard to endogenous *N. sativa* seed oils is incorrect as evidenced by Ramadan and Mörsel (Nahrung/Food) (2002) Ramadan and Mörsel (Eur. Food Res.) (2002), Ramadan (2003) and Nickavar et al. (2003) which all disclose that *N. sativa* seed oil contains approximately 60% linoleic acid as well as approximately 20% oleic acid (see, Ramadan and Mörsel (Nahrung/Food) (2002), Table 2,. Ramadan and Mörsel(Eur. Food Res.) (2002) Table 1, and Nickavar et al. (page 630).

It is deemed that Figure 1 of Kandill is fully enabled in that one of skill in the art could easily prepare the composition according to the figure. It is noted that the compositions as prepared by Figure 1 are the same compositions as Instantly claimed. Applicant argues that "...the oily extract of *N.sativa* L. of the instant invention is preferably obtained through successive extraction 'in a percolator until exhaustion....in order, petroleum ether...hexane...methanol and water" (p. 9, Remarks). However, Applicant has misquoted the specification: the specification actually states "....methanol ***or*** water" (emphasis added) thereby indicating that separate extractions were occurring. It is also clear from the paragraph that follows, that Applicant actually subjected the intermediate petroleum ether product to chromatography on silica gel (page 14, Specification). Further, there is no indication that this protocol produces the composition of the entire *claimed* invention. The closest protocol which can be determined which actually produces the product of the claimed invention such as claims

3-5 and 20-22 is captured as Applicant's figure 1 which specifically states that after hexane or petroleum ether extraction the composition is allowed to cool and the solid fat portion containing resins, tocopherols, aglycons, short chain fatty acids and hydrocarbons are removed by this process. There is no indication anywhere in the specification that a petroleum ether extraction followed by silica gel chromatography will remove the solid fats; especially considering that the solid fats have not been elucidated within the Instant specification. Again, it is noted that Figure 1 of Kandill is the same chart diagram as found in the Instant specification and therefore makes obvious the Instant claims.

Applicant argues that Kandil did not disclose any pharmaceutical use and that "there is no teaching or suggestion in Kandil to isolate the lipid intermediate and formulate it for topical administration" (p. 10, Remarks). However, this remark is rendered moot in light of the new rejection set forth under this statute.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

January 17, 2007